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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,325	05/02/2005	Gary Wayne Goodson	PU5025USW	5293

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,325	GOODSON ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 4 - 9, 11 - 15, 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4 - 9, 11 - 15, 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 23, 2009 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim1, 2, 4 – 9, 11 – 15 and 17 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 16 of U.S. Patent No. 6,113,920 in view of Rudnic et al. (US 2002/0068085). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 27, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that neither reference discloses a formulation of zidovudine [compound of subparagraph i)] and lamivudine [the second compound of subparagraph ii)] for once daily administration. The compositions provide for the immediate release of zidovudine and lamivudine followed by controlled release

of zidovudine. COMBIVIR® is one tablet twice daily and because of the convenience and compliance essential in HIV treatment, if the combination were obvious, then one may have expected a once daily lamivudine/zidovudine product.

These arguments are not persuasive. "For once daily administration" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentable distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The composition disclosed in US'920 in view of Rudnic et al. could be administered once per day and thus this limitation is not sufficient to distinguish between the instant claims and the claims of US'920 in view of Rudnic et al. The absence of an anticipatory reference is not evidence that the invention would not have been obvious.

Claim Rejections - 35 USC § 112 – 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 4 – 9, 11 – 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a written description rejection. Applicant has not provided sufficient discloses to support the full breadth of compositions that exhibit controlled release of zidovudine wherein release occurs with 3 – 6 hours and immediate release of lamivudine and zidovudine for once daily administration. The specification provides one specific example of a formulation, and although release data is not provided, presumable meets the release limitations set forth within the instant claims. This one formulation uses one combination of particular controlled release polymers. This one example is insufficient to provide written description support for all possible controlled and immediate release formulations with the two recited active ingredients.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2, 4 – 9 and 11 – 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the limitation "said composition providing for the release of zidovudine within 3 – 6 hours" and how this limitation fits with the other limitations. While no exact definition of immediate release has been provided by Applicant, a delay of 3 hours between administration to a patient and release occurring would not be considered by one skilled

in the art to be immediate release. Thus, this time appears to contradict subparagraph ii) in which an immediate release portion of zidovudine must be present. The starting point of the time frame measurement is unclear. It is also unclear if the release of the active ingredient begins within 3 – 6 hours and can continue beyond 6 hours or if the entire release of the drug must occur within the 3 – 6 hour time frame. Because of the pharmacokinetic properties of some drugs, a once daily administration form can be achieved for some drugs when all of the drug is released within 6 hours of administration. Also, there is a lack of antecedent basis for "zidovudine" in the last line of claim 1 as the name 3'-azido-3'deoxythymidine is used previously in the claims. To avoid confusion for those less familiar with these compounds, it is suggested that Applicant select one name for use throughout the claim or indicate the equivalence of these names in the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2, 4, 6 – 9, 11 – 15 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (US 2002/0068085) in view of Cameron et al. (WO 92/20344). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 27, 2008 and those set forth below.

Applicants traverse this rejection on the grounds that the reference does not disclose a pharmaceutical composition of a controlled release formulation of zidovudine together with an immediate release formulation of lamivudine and zidovudine for once daily administration. The short half-life of zidovudine in the blood and preferential absorption in the upper gastrointestinal tract preclude once daily administration. COMBIVIR® is one table twice daily and because of the convenience and compliance

essential to HIV treatment, if the combination were obvious, the one may have expected a once daily lamivudine/zidovudine product.

These arguments are not found persuasive. Rudnic et al. discloses both immediate and delayed release zidovudine formulations, including enteric coated (examples 36 – 39, ¶ [0063]). Because of the physical structure and coating material, release of the zidovudine will be delayed until the dosage form exits the stomach, at which time the enteric coating will dissolve in the less acidic small intestine, allowing release and absorption to take place in the upper gastrointestinal tract within 3 – 6 hours after administration of the dosage form. Taken together, Rudnic et al. and Cameron et al. discloses both the different release profiles and the specific combination of lamivudine and zidovudine required by Applicant in the instant claims.

"For once daily administration" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentable distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The compositions taught by Rudnic et al. and Cameron et al. can be administered once per day. The absence of an anticipatory reference is not evidence that the invention would not have been obvious.

12. Claims 1, 2, 4 – 9, 11 – 15 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al. and Cameron et al. further in view of Liu et al. (US

5,009,895). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 27, 2008 and those set forth below.

In addition to the arguments presented above, Applicant argues that the compositions of Liu et al. only contain one active ingredient, such as ibuprofen.

This argument is not found persuasive. The combination of ingredients and release profiles are taught by Rudnic et al. and Cameron et al. Liu et al. is relied upon for the teachings of a combination of HPMC with different viscosities providing controlled release of the active ingredient. The controlled release will occur whether one or more than one active ingredient is present. Therefore, this rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW